DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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January 15, 2015

Boston Scientific Corporation
Nikki M. Wahlberg
Regulatory Affairs Specialist
One Scimed Place
Maple Grove, MN 55311-1566

Re: K143587
Trade/Device Name: ChoICE, Mailman, Luge, ChoICE PT, ChoICE PT Graphix Guide Wires
ChoICE Magnet, Mailman Magnet, Luge Magnet, ChoICE PT Magnet, PT Graphix Magnet Guide Wires
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guide wire
Regulatory Class: Class II
Dated: December 17, 2014
Received: December 18, 2014

Dear Ms. Wahlberg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Melissa A. Torres -S

For Bram Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143587

Device Name
ChoICE™, Mailman™, Luge™, ChoICE™ PT, and PT Graphix™ Guide Wires
ChoICE™ Magnet, Mailman™ Magnet, Luge™ Magnet, ChoICE™ PT Magnet, and PT Graphix™ Magnet Guide Wires

Indications for Use *(Describe)*
Boston Scientific ChoICE™ PT, PT Graphix™, ChoICE, Luge, and Mailman Guidewires with ICE Hydrophilic Coating are intended to facilitate the placement of balloon dilatation catheters or other therapeutic devices during PTCA or other intravascular interventional procedures. They are not intended for use in the cerebral vasculature.

Boston Scientific ChoICE™ PT Magnet, PT Graphix™ Magnet, ChoICE Magnet, Luge Magnet, and Mailman Magnet Guidewires with ICE Hydrophilic Coating are intended to facilitate the placement of balloon dilatation catheters or other therapeutic devices during PTCA or other intravascular interventional procedures. They are not intended for use in the cerebral vasculature.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
per 21 CFR §807.92

Sponsor: Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752

Contact Person: Nikki M Wahlberg

Phone Number: 763-494-2381

Fax Number: 763-494-2981

Prepared: December 17, 2014

Trade Name: ChoICE™, Mailman™, Luge™, ChoICE™ PT, and ChoICE™ PT Graphix Guide Wires

ChoICE™ Magnet, Mailman™ Magnet, Luge™ Magnet, ChoICE™ PT Magnet, and PT Graphix™ Magnet Guide Wires

Common Name: Catheter Guide Wire

Classification: II

Product Code: DQX per CFR Part 870.1330

Primary Predicate Device:

PT² Guide Wire and AddWire™ Extension Wire (K030617, 21 May 2003)

Reference Predicate Device:

Luge Guide Wires (K973945, 12 January 1998)

Mailman (ChoICE Family Super Support/Super Support II) Guide Wires (K964551, 21 May 1997)

ChoICE Plus, ChoICE PT Plus, ChoICE PT Graphix (K965023, 3 April 1997)

ChoICE Family of Guide Wires (K970244, 28 March 1997)

ChoICE PT Graphix (K962572, 17 December 1996)

Device Description:

The Boston Scientific ChoICE™, Mailman™, Luge™, ChoICE™ PT, and ChoICE™ PT Graphix Guide Wires with ICE® Hydrophilic Coating are available with a nominal diameter of 0.014 in (0.37 mm) and in nominal lengths of 182 cm or 300 cm. These guide wires contain a 304 stainless steel core wire. The proximal section of the core wire of all models is coated with polytetrafluoroethylene (PTFE) for lubricity. The distal end of the core wire is formed (flattened) to allow for shaping. All models are available with a shapeable Straight Tip or a preformed “J” Tip to address user preference. Varying tapers along the distal core wire and differing tip materials (spring coil or polymer) provide combinations of rail support and tip flexibility to address user requirements. The 182 cm guide wires are designed with an extension section for exchange of Over-the-Wire systems by using either the MAGNET Exchange Device or the AddWire™ Extension Wire. The 300 cm guide wires allow exchange of therapeutic devices without the use of an extension wire or exchange system.

Indications for Use / Intended Use:

Boston Scientific ChoICE™ PT, PT Graphix™, ChoICE, Luge, and Mailman Guidewires with ICE Hydrophilic Coating are intended to facilitate the placement of balloon dilatation catheters or other therapeutic devices during PTCA or other intravascular interventional procedures. They are not intended for use in the cerebral vasculature.

Boston Scientific ChoICE™ PT Magnet, PT Graphix™ Magnet, ChoICE Magnet, Luge Magnet, and Mailman Magnet Guidewires with ICE Hydrophilic Coating are intended to facilitate the placement of balloon dilatation catheters or other therapeutic devices during PTCA or other intravascular interventional procedures. They are not intended for use in the cerebral vasculature.

Substantial Equivalence:

The ChoICE™, Mailman™, Luge™, ChoICE™ PT, and ChoICE™ PT Graphix Guide Wires incorporate substantially equivalent designs, device materials, manufacturing processes, fundamental technology, sterilization process, and intended use as those in the predicate devices. The 182 cm guide wires are designed with an extension section for exchange of Over-the-Wire systems by using either the AddWire™ Extension Wire similar to the design of the predicate device PT² Guide Wire (K030617) or the MAGNET Exchange Device similar to the design of the reference predicates.

Summary of Non-Clinical Testing:
Design verification testing was performed to verify that the performance of the ChoICE, Mailman, Luge, ChoICE PT, and ChoICE PT Graphix Guide Wires remains substantially equivalent to the predicate device.

Specifically, the following design verification and validation testing was performed:

- Torqueability
- Exchange System Coupling Strength
- Exchange System Connectability

Biocompatibility Testing:
The ChoICE, Mailman, Luge, ChoICE PT, and ChoICE PT Graphix Guide Wires were compared to the predicate devices. Based on similarities of the materials used in the subject devices compared with the predicates, the following biocompatibility testing was conducted:

- Cytotoxicity
- USP Physiochemical Test
- Latex

Summary of Clinical Testing:
Clinical Evaluation was not required for these devices.

Conclusion:
The ChoICE™, Mailman™, Luge™, ChoICE™ PT, and ChoICE™ PT Graphix Guide Wires have the same intended use and technological characteristics such as components, materials, sterilization method, shelf life and operating principle as the predicate devices. Performance data demonstrates that the device functions as intended, and is as safe and effective as the predicate devices.